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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,832	06/01/2001	Michel Sadelain	830002-2003.1	3724

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NEW YORK, NY 10151

EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/872,832

**Applicant(s)**

SADELAIN ET AL.

**Examiner**

G. R. Ewoldt, Ph.D.

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003 and 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's Election of Group III, filed 8/01/03, and election of species, filed 2/27/04, is acknowledged. In view of Applicant's arguments the restriction is hereby vacated. A new restriction follows. The Examiner apologizes for any inconvenience or delay.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-40, drawn to an artificial antigen presenting cell, classified in Class 435, subclasses 348, 352, 354, and 366.

II. Claims 41 and 42, drawn to method of activating cytotoxic T lymphocytes (CTLs), classified in Class 424, subclass 185.1.

III. Claims 43 and 44, drawn to a CTL, classified in Class 424, subclass 93.71.

IV. Claim 45, drawn to a method of treating a patient comprising administering AAPCs, classified in Class 424, subclass 185.1.

V. Claims 46 and 47, drawn to a method of treating a patient comprising administering CTLs, classified in Class 424, subclass 93.71.

VI. Claim 48, drawn to a method of screening for accessory molecules, classified in Class 435, subclass 7.2.

VII. Claims 49-53, drawn to a method of screening for T cell-specific antigens, classified in Class 435, subclass 7.1.

VIII. Claims 54-60, drawn to a method of identifying CTLs specifically activated against a known T cell antigen, classified in Class 435, subclass 7.1.

3. Invention I and III are different products. They are distinct because their structures and/or modes of action are different, i.e., AAPCs and CTLs comprise different cell types. Therefore, the Inventions are patentably distinct.

4. Inventions II and IV-VIII are different methods. The methods employ different reagents, different method steps, and result in different endpoints. For example, Invention III

employs AAPCs and results in CTLs whereas Invention VI employs AAPCs and CTLs and results in the identification of an accessory molecule. Also note that Inventions II, VI, VII, and VIII comprise *in vitro* methods which comprise significantly different considerations and limitations than do the *in vivo* methods of Inventions IV and V. Therefore they are patentably distinct.

5. Inventions I and III, and II and IV-VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in materially different processes, such as to produce antibodies.

6. This application contains inventions drawn to patentably distinct species. Should Applicant elect Group I, Applicant is further required under 35 U.S.C. § 121 to elect a specific embodiment of AAPC for examination. Said embodiment comprises:

- A) a **specific** cell source, such as one of those listed in Claim 4,
- B) a **specific** cell type, such as one of those listed in Claim 8,
- C) a **specific** accessory molecule, or a **specific** combination thereof, such as one or more of those listed in Claim 14,
- D) a **specific** HLA, such as one of those listed in Claims 26-32,
- E) a **specific** T cell epitope, such as one of those listed in Claims 26-32,
- F) and list all Claims readable thereon including those subsequently added. Currently all claims are generic.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different cell sources comprise different biological properties that would likely result in different immunological responses. For example, a murine cell would result in a

xenogeneic response in a human patient. The different cell types comprise different biological properties, e.g., a transformed cell line would comprise significantly different biological properties than would a keratinocyte. The different accessory or HLA molecules comprise discrete sequences that themselves are patentably distinct and would result in different immunological responses if employed in the claimed AAPC. The different T cell epitopes would activate separate and distinct subsets of CTLs. Therefore, the species are independent and patentable over one another.


8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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